Second, McKesson-Aurora routinely manipulated the thresholds. It would often preemptively increase the thresholds of its customers on particular drugs before the customers had even submitted a TCR seeking a threshold increase. These preemptive threshold increases were often in response to either the threshold warning reports or omit reports — the very reports that McKesson was supposed to rely upon to "investigate customer activity." For instance:

- In an email dated February 28, 2012, Jake Kramer, Distribution Center Manager for McKesson-Aurora, emailed Robert Perrich, Operations Manager at McKesson-Aurora, and asked the following question: "Can you call Prescription Shop and see if they need an adjustment? He wasn't in when I called today and should be there by now . . . ." *See* Attachment 10, Bates No. MCK_00030152.

- In email dated December 27, 2012, Perrich sent an email to Beau Bradley, Inventory Manager, and asked: "REDACTED is now on here for Hydrocodone…also we have REDACTED. Do you think we should do ***pre-emptive*** TCR for these two?" *See* Attachment 11, Bates No. MCK_00010740 (emphasis added).

Time and time again, McKesson-Aurora increased a customer's threshold in a particular month so that the customer did not exceed that threshold and thus trigger McKesson-Aurora's obligation to conduct a Level 2 or Level 3 review (much less file a SOR with the DEA). McKesson-Aurora simply kept raising the threshold bar so that it accommodated the customer's ordering pattern without triggering review or restricting any customer's access to as much controlled substances as it wanted to purchase. We have attached charts for several pharmacies that demonstrate this pattern. *See* Attachment 12, Blende Pharmacy (hydrocodone), Dale's Pharmacy (oxycodone), Beattie's (oxycodone), Todd's Pharmacy (oxycodone).

Third, McKesson-Aurora was often willing to increase a pharmacy's threshold for the flimsiest of reasons and without adequate investigation. To give just a few of many examples:

- Dale's Pharmacy requested an increase of its oxycodone threshold on December 27, 2010. Dale's proffered justification for the TCR was "[n]ormal business with increased volume during the holidays." *See* Attachment 13, Bates No. MCK_000168027. Although there were only four days remaining in the month until Dale's oxycodone would be reset, McKesson-Aurora approved an 8,000 dosage unit increase of Dale's oxycodone threshold, increasing the threshold by 20.5 percent from 39,000 to 47,000 dosage units.

- From June 2010 through November 2010, McKesson-Aurora justified multiple threshold increases for Dale's Pharmacy based upon an alleged "influx of customers" due to the closure of a neighboring pharmacy in Fort Lupton. Several of the TCR's for Dale's justified requests for threshold increases on the grounds that the "API Pharmacy" had stopped selling controlled substances. In point of fact, the API Pharmacy had closed seven years earlier in 2003. The Pharmacy at Salud, another pharmacy in Fort Lupton, did stop selling controlled substances for 19 days in June 2010. However, McKesson-Aurora allowed Dale's to rely on this closure excuse for continued threshold increases for another four months, even after the Pharmacy at Salud was back up and running. *See* Attachment 14, Bates No. MCK_168019-168020; MCK_169024-168025.

- McKesson-Aurora justified a 7,000-dosage unit increase of oxycodone to Beattie's Pharmacy in Brighton on the grounds that the pharmacy had been robbed. On July 9, 2009, Beattie's was robbed of 2,448 dosage units of oxycodone. In response, Beattie's requested a threshold increase of 6,000 dosage units. Rather than simply raising the threshold to allow for the replacement of the 2,448 pills that had been stolen, McKesson-Aurora authorized a ***7,000*** dosage unit increase to Beattie's oxycodone threshold — 1,000 dosage units more than the pharmacy even requested and 4,500 dosage units more than was warranted by the robbery it used to justify the request.

Fourth, our review of McKesson-Aurora's due diligence files reveals that McKesson-Aurora frequently failed to provide justifications as to why a customer's threshold was being increased. This directly contradicted the CSMP, which requires searching review and emphasizes the duty to know the customer. *See* Attachment 7.

In sum, thresholds that were originally intended to trigger an investigation that could result in a suspicious order being reported to the DEA never served this purpose. McKesson did not "set" and then "maintain" its thresholds, as required by its CSMP. The thresholds did not meaningfully restrict McKesson-Aurora's customers from obtaining controlled substances. Thresholds were moved to accommodate whatever purchasing occurred, or they were set so high that they never triggered any review. In fact, as explained below in Section V.C.1, *infra*, we even have evidence that thresholds were frequently exceeded without consequence, given that McKesson-Aurora neither meaningfully investigated the threshold incursion nor submitted any suspicious order reports to the DEA.

2. *McKesson-Aurora Did Not Actually Use the Three-Level Review Process to Carefully Review Potentially Suspicious Orders.*

The CSMP set up the Level Review process described in Section IV.E, *supra*. However, our investigation found no evidence that McKesson-Aurora ever conducted a Level 2 or Level 3 review for ***any*** of its pharmacy customers between 2008 and 2013.

Although McKesson-Aurora did, from time to time, conduct Level 1 reviews, it often did not take adequate time to conduct a ***meaningful*** Level 1 review focused on detecting suspicious orders. For example, on approximately six separate occasions, McKesson-Aurora completed an omit report, Level 1 review, and TCR for Blende Drug, all on the same date. Likewise, on seven separate occasions, McKesson completed an omit report, Level 1 review, and TCR for JB Pharmacy, all on the same date. Performing the review on the same day that the threshold change was approved indicates that McKesson-Aurora's review of the proffered justification for the threshold change was cursory, and that the company was not interested in digging too deeply to determine if the justification was valid.

Under the CSMP, the omit report was supposed to trigger an investigation into whether an order was suspicious. But in practice McKesson-Aurora ignored the CSMP. Instead of looking at omitted orders to see if those orders were suspicious, McKesson-Aurora looked at omit reports to see if the customers needed a threshold increase. *See* Attachment 10. Essentially, the omit report became a sales tool, rather than a way of monitoring orders to try to detect and prevent diversion. And on those occasions when a pharmacy said that it did not need a threshold increase, McKesson-Aurora did nothing further to investigate whether the threshold incursion involved a suspicious order and, following an investigation, report that order as suspicious.

3. *McKesson-Aurora Failed to Conduct Adequate Due Diligence.*

McKesson-Aurora also failed to conduct due diligence, even when faced with possible diversion. Take, for example, the manner in which McKesson-Aurora conducted due diligence on JB Pharmacy, one of its independent pharmacy customers located in Pueblo, Colorado. In answering the question on a Pharmacy Questionnaire about the monthly dosage units dispensed for hydrocodone and oxycodone, JB Pharmacy reported 15,100 and 17,500 dosage units, respectively. To explain why its numbers were greater than 5,000 dosage units, JB Pharmacy stated that "Overusage by neurologists + other prescribers." *See* Attachment 15, Bates No. MCK_000413-000420. This "Overusage" comment prompted an email exchange between Tom McDonald, McKesson's DRA for the Western Region, and Jake Kramer, McKesson-Aurora's Distribution Manager. *Id.* McDonald questioned Kramer as to JB Pharmacy's stated explanation, and Kramer justified continuing to do business with JB Pharmacy in part

because "[t]his is a long time and very influential independent, basically what he says[,] so goes our entire independent customer base." *Id.* McDonald then approved the TCR. *Id.* The fact that this particular pharmacy was a "very influential" customer should have had no weight in McKesson-Aurora's determination about whether it was filling suspicious orders and whether McKesson-Aurora should accommodate (by raising its threshold) the "overusage" of controlled substances that this pharmacy was reporting.

Although the CSMP discussed the possibility of conducting site visits so that McKesson-Aurora could better understand their customers' business, these visits appear to have been largely perfunctory and well recognized as such. For instance, on August 19, 2010, Jake Kramer sent an email to John Schultz, a sales manager handling customers located in southern Colorado, with a list of customers that Kramer wanted to visit. Kramer asked Schultz to set up the site visits. In this email, Kramer stated "Below is a list of 'must-see' accounts. Their monthly thresholds are at a level [sic] I would like to visit them again and see the business for myself. They have 'absolutely' nothing to worry about but part of the CSMP requirement is that I visit accounts over a certain threshold." *See* Attachment 16, Bates No. MCK_00168442-00168444.

McKesson-Aurora also failed to conduct due diligence when it came to analyzing a customer's ratios of controlled substances to non-controlled substances, and ratios of oxycodone to other controlled substances. Analyzing these ratios is one way to determine whether diversion might be occurring at a pharmacy; after all, if a pharmacy customer was purchasing all of its drugs exclusively from McKesson, and 90 percent of its purchases were controlled substances and only 10 percent were non-controlled substances, that might be a warning to McKesson that it should investigate the pharmacy's transactions to ensure its sales were not resulting in diversion. At one point, Tom McDonald had provided Jake Kramer with data showing a McKesson-Aurora customer with a high ratio of oxycodone to non-controlled substances. This, apparently, did not trigger any alarm for McKesson-Aurora because high ratios were the rule rather than the exception. On September 26, 2012, Jake Kramer wrote an email to Tom McDonald in which he stated, "Everybody is high Tom; are we suppose [sic] to cut everyone off?" *See* Attachment 17, Bates Nos. MCK_00167825–00167827.

4. *McKesson-Aurora Failed to Provide Its Sales Representatives With Adequate Guidance on How to Implement the CSMP.*

As part of our investigation, we have interviewed several former sales representatives. These sales reps have all consistently explained that the personnel in the distribution center's warehouse were responsible for monitoring orders to determine if any particular order was suspicious. While a great deal of effort went into getting sales reps to increase sales, little or no effort was spent on training these sales reps to ensure compliance with the CSA.

The CSMP provides little to no guidance to the sales reps or the distribution center management regarding the identification of potentially suspicious orders. Our investigation revealed that the CSMP was nothing more than a "how to" guide for filling out CSMP paperwork, rather than a tool by which McKesson employees could evaluate potentially suspicious orders.

Additionally, our investigation revealed that McKesson had a separate CSMP Standard Operating Procedure ("SOP") for its Service First employees, who are the McKesson sales personnel responsible, in part, for implementing the CSMP. Nowhere in the 14-page document does McKesson give guidance as to how to detect a suspicious order. *See* Attachment 18. Instead, the SOP directs Service First representatives to preemptively ask customers for a threshold change whenever a customer approaches its monthly threshold. Accordingly, the separate CSMP SOP directed these Service First representatives to bypass the thresholds, rather than hold customers to those thresholds or figure out why the customers had reached the thresholds.

5. *McKesson-Aurora Gave Its Employees Guidance on How to Avoid Creating Adverse Evidence.*

The CSMP Operations Manual contains a troubling directive to McKesson employees to communicate in a manner that will not require the company to report suspicious orders to the DEA. The Operations Manual directs McKesson employees to "[w]rite information as if it were being viewed by the DEA," and it specifically instructs employees to "refrain from using the word 'suspicious' in communications" describing customer orders. *See* Attachment 7, at Section 4. As the Manual explains, "Once McKesson deems an order and/or customer suspicious, McKesson is required to act. This means all controlled substance sales to that customer must cease and the DEA must be notified." *Id.* Language such as this confirms that McKesson understood that it has an obligation to report suspicious orders, but that it consciously took steps to avoid having to report.

C. Many Suspicious Orders Went Unreported.

Following the execution of the Administrative Inspection Warrant and the subpoena in March 2013, the United States has focused on 15 of McKesson-Aurora's pharmacy customers. The pharmacies comprising this sample were selected on a variety of criteria, including McKesson-Aurora's own representations about its Top 50 largest purchasers of oxycodone and hydrocodone.

Our analysis of this small sample of McKesson-Aurora's 530 customers shows that there were many orders that McKesson-Aurora should have reported to the DEA as suspicious, under the definition set forth at 21 C.F.R. § 1301.74(b) and the Rannazzisi letter dated December 20, 2007 (Attachment 4). However, not only did McKesson-

Aurora not report ***any*** of these orders to the DEA, McKesson-Aurora's due diligence files show that the company did nothing to investigate whether these orders were suspicious.

1. *McKesson-Aurora Failed to Report Orders That Exceeded the Threshold.*

The CSMP Operations Manual states that McKesson distribution centers are not to fill orders that exceed a customer's threshold for a particular drug. However, our analysis shows that McKesson-Aurora routinely broke this rule. We have uncovered numerous examples of McKesson-Aurora's pharmacy customers ordering more dosage units than their established thresholds, and McKesson-Aurora filling those orders without reporting them to the DEA as suspicious. For example:

- Lajara Pharmaceutical Center in La Jara, Colorado exceeded its monthly threshold for oxycodone purchases in March 2010, January 2012, and March 2012. *See* Attachment 19, Lajara Pharmaceutical Center (oxycodone).

- Todd's Harvard Park Pharmacy in Denver exceeded its monthly oxycodone thresholds on eight separate occasions: March 2010, August 2010, May 2011, November 2011, February 2012, July 2012, August 2012, and May 2013. *See* Attachment 12.

- We have seen examples of pharmacies exceeding their thresholds by hundreds and thousands of dosage units. For instance, Valley Wide Pharmacy in Alamosa, Colorado exceeded its oxycodone threshold by 2,000 dosage units in September 2011 and 1,500 dosage units in February 2012. *See* Attachment 20, Valley Wide Pharmacy (oxycodone).

The due diligence files for Lajara Pharmaceutical Center, Todd's Harvard Park Pharmacy, and Valley Wide Pharmacy provide no explanation as to why McKesson-Aurora allowed the pharmacies to breach their thresholds. Nor do the files give any indication that McKesson-Aurora did anything to investigate whether these or other orders were suspicious. No suspicious orders were reported to the DEA for these pharmacies for any of these months.

2. *McKesson-Aurora Failed to Report Orders of Unusual Size.*

Under 21 C.F.R. § 1301.74(b), suspicious orders are defined to include "orders of unusual size." Our investigation has demonstrated that McKesson-Aurora filled many orders of unusual size that it did not report to the DEA, including:

- In November 2011, Chase Pharmacy in Byers, Colorado placed and McKesson-Aurora filled orders for 26,000 dosage units of oxycodone. This amount was more than double the 10,400 dosage units of oxycodone that Chase had ordered in October 2011, and 5,000 dosage units more than the 21,000 dosage units Chase had ordered in September 2011. *See* Attachment 21, Chase Pharmacy (oxycodone).

- Valley Wide ordered 4,900 dosage units of oxycodone in August 2011. In September 2011, Valley Wide ordered 12,000 dosage units. This amount was 3,500 dosage units larger than Valley Wide's highest prior order of 8,500 dosage units in March 2011. *See* Attachment 20.

- Alamosa Pharmacy in Alamosa, Colorado ordered 2,300 dosage units of hydrocodone in February 2010. The following month, the pharmacy more than doubled its purchases, ordering 5,400 dosage units of hydrocodone. *See* Attachment 22, Alamosa Pharmacy (hydrocodone).

- Blende Pharmacy in Pueblo, Colorado almost quadrupled its order of hydrocodone without raising a red flag at McKesson-Aurora. Blende ordered 4,100 dosage units in June 2012, and 16,300 dosage units in July 2012. *See* Attachment 12.

The geographic locations and surrounding populations of certain pharmacy customers should have indicated to McKesson-Aurora that the size of their controlled substance orders were suspicious. For instance:

- La Jara, Colorado is located in a very rural area of the state. The town has a population of 818 people, of whom 80% (654 people) are adults, according to the 2010 U.S. Census. Yet the Lajara Pharmaceutical Center was routinely among McKesson-Aurora's top purchasers for various controlled substances alongside pharmacies servicing much more densely populated areas, purchasing 240,100 dosage units of oxycodone and 110,460 dosage units of hydrocodone in 2012. It was highly suspicious that this pharmacy was ordering controlled substances in amounts that were disproportionate to the population it served.

- Chase Pharmacy is located in Byers, Colorado, which has a population of 1,160, 74% of whom were adults, according to the 2010 U.S. Census. In 2012, Chase purchased 171,700 dosage units of oxycodone and 107,600 dosage units of hydrocodone from McKesson-Aurora, amounting to 200 dosage units of oxycodone and 125 dosage units of hydrocodone for every adult in Byers in 2012.

Despite McKesson-Aurora's "know your customer" directive, it is clear that McKesson-Aurora did not even use plain common sense when it came to scrutinizing its customers' purchases, let alone engage in meaningful attempts to know its customers. Compare the total purchases made by Dale's Pharmacy, which is located in Fort Lupton, to another McKesson-Aurora customer, Safeway, which is located just down the road in Fort Lupton. Dale's was ordering anywhere from seven to 12 times as much oxycodone, and about three times as much hydrocodone, as the Fort Lupton Safeway between 2009 and 2011. *See* Attachment 23, Dale's v. Safeway Yearly Sales. These sales numbers are unusual, given that independently owned pharmacies like Dale's do not typically out-order national chain pharmacies like Safeway. Despite these numbers, McKesson-Aurora did not file any suspicious order reports on Dale's with the DEA until March 2012.

3. *McKesson-Aurora Failed to Report Orders of Unusual Frequency.*

McKesson-Aurora also failed to report orders of unusual frequency to the DEA, in violation of 21 C.F.R. § 1301.74(b). For instance, our analysis shows that Blende Pharmacy typically submitted to McKesson-Aurora anywhere from one to five orders of hydrocodone each day. *See* Attachment 24, Blende Pharmacy (hydrocodone frequency chart). On November 23, 2010, Blende placed 14 orders of hydrocodone in a single day. *Id.* Likewise, on March 20, 2012, Blende placed 25 orders of hydrocodone — over five times more than Blende's typical number of orders — in a single day. *Id.* McKesson-Aurora reported none of this conduct to the DEA as suspicious.

VI. McKesson-Aurora's Failure to Identify and Report Suspicious Orders Caused Significant Public Harm.

This is not a CSA investigation where the harm to the public is merely theoretical. McKesson-Aurora's calculated business decision not to report suspicious orders had tragic and severe consequences.

Thus far, our investigation has identified at least nine individuals who died of a drug overdose from prescription drugs purchased from several different pharmacies that had purchased those controlled substances from McKesson-Aurora.

In addition, the DEA uncovered a dangerous drug-trafficking organization ("DTO") operated by Robin Steinke in and around Denver that relied upon the Platte Valley Family Pharmacy in Brighton for its supply of illegally obtained controlled substances. Jeffrey Clawson, the owner of the pharmacy and a DEA registrant, voluntarily spoke with DEA investigators and admitted that he was involved in filling fraudulent prescriptions for Steinke and individuals associated with Steinke. Clawson admitted that this conduct occurred from April 2010 through May 2012, when he voluntarily surrendered his DEA registration. During this same time period, McKesson-Aurora was the sole supplier of drugs to Platte Valley Family Pharmacy.

McKesson-Aurora should have been paying especially close attention to Clawson and the purchases made by the Platte Valley Family Pharmacy between 2008 and 2012. That is because Clawson is the former pharmacy manager of the Brighton Family Pharmacy, which is one of the three pharmacies that were the subject of the Colorado covered conduct in the 2008 Settlement Agreement. However, despite vast increases in the amounts of controlled substances (particularly oxycodone) ordered by Platte Valley Family Pharmacy, McKesson-Aurora never reported ***any*** suspicious activity to the DEA during the time that the pharmacy was serving as a source of supply of controlled substances for the DTO.

A Colorado state grand jury subsequently indicted Clawson, Steinke, and 13 others for Racketeering, Conspiracy to Distribute Controlled Substances, and Distribution of Controlled Substances. *See* Attachment 25, Indictment. Significantly, McKesson was also mentioned in the indictment:

> A key issue during this time period was that McKesson, like all other DEA registered suppliers, had an obligation under the federal Controlled Substances Act, to report to DEA suspicious sales or orders of controlled substances. The Grand Jury learned of evidence demonstrating that Clawson's Platte Valley Pharmacy engaged in the regular purchase of Oxycodone from McKesson that was either unusually large, unusually frequent, and/or which substantially deviated from the normal pattern typically observed for comparable pharmacies in the area in and around Brighton, Colorado. From 2008-2011 the percentage increase for Oxycodone 30mg orders supplied by McKesson to Platte Valley Pharmacy was approximately 1,469%. Further, evidence was presented that the DEA did not receive any reports from McKesson regarding Platte Valley Pharmacy's purchase of Oxycodone that were arguably suspicious in terms of quantities and frequency.

Id. at 12.

McKesson-Aurora's due diligence file for Platte Valley Family Pharmacy provides countless indications of suspicious ordering patterns, all of which were ignored by McKesson-Aurora personnel. In addition, though McKesson was aware that Clawson had previously served as the pharmacy manager at Brighton Family Pharmacy, which was one of the Colorado pharmacies involved in the 2008 Settlement Agreement, this fact

did not raise any red flags regarding the large amounts of oxycodone being ordered by Clawson at Platte Valley Family Pharmacy.[4]

VII. Penalty.

As a DEA registrant, McKesson-Aurora is required by the CSA to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and to "inform" the DEA of those suspicious orders when discovered. 21 C.F.R. § 1301.74(b). Any such "refus[al] or negligent[] fail[ure] to make, keep, or furnish any . . . report . . . or information required" by the CSA is a violation of federal law and punishable by a civil penalty of up to $10,000. 21 U.S.C. §§ 842(a)(5) and (c)(1)(B). Such punishment is intended to impress upon registrants the importance of their role in maintaining effective controls against diversion.

McKesson's payment of $13,250,000 in 2008 for failing to file suspicious order reports did little to impress upon the company the concrete, public-safety consequences of its failure to obey the law. Given that, and applying the penalty factors set forth above, we will seek at trial the maximum civil penalty permissible for each instance in which McKesson-Aurora failed to inform the DEA of a suspicious order.[5]

VIII. Conclusion.

McKesson-Aurora made a calculated business decision to avoid reporting suspicious orders. McKesson-Aurora's failure to report suspicious orders to the DEA is particularly egregious for two reasons.

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[4] We are also aware of another drug-trafficking organization — totally separate from the Steinke DTO discussed above — that was based in and around Alamosa, Colorado. This DTO was operating in 2012. We have uncovered evidence to show that many persons associated with this DTO filled prescriptions at Lajara Pharmaceutical Center, which partly accounts for that rural pharmacy's unusually large orders. Again, McKesson-Aurora did not alert the DEA about any suspicious orders placed by the Lajara Pharmaceutical Center, even after the media broke the story on October 11, 2012, that the individuals associated with the DTO had been arrested and charged.

[5] The United States Attorney's Office for the District of Colorado is not the only such office currently investigating McKesson's conduct. This civil penalty is, of course, separate and apart from any other civil penalties that could be pursued by other U.S. Attorneys across the country, all of whom may bring separate cases against McKesson. All of these cases are also separate and apart from administrative actions that could be brought directly by the Drug Enforcement Administration to revoke or suspend McKesson-Aurora's DEA Certificate of Registration and the Certificates of Registrations of McKesson's other distribution centers.

First, what the law mandates of distributors like McKesson-Aurora is minimal and easily accomplished. Unlike some regulatory regimes in which the government forces companies to submit to some time-consuming, burdensome, and cost-prohibitive enforcement process, what the DEA asks its registrants to do with respect to suspicious orders is quite simple: design a system that identifies suspicious orders and report any suspicious orders to the DEA. And yet, for several years, McKesson-Aurora never bothered to report to the DEA what were clearly suspicious orders.

Second, McKesson-Aurora — of all DEA registrants — should have known better. McKesson paid $13,250,000 and entered into the 2008 Settlement Agreement and the MOA with the United States for its failure to report earlier suspicious orders by pharmacies. McKesson then designed a compliance system, the CSMP, to make it even clearer and easier to obey this simple reporting requirement. McKesson-Aurora, however, then immediately set its mind to disabling this system. An illustrative and predictable result was that McKesson-Aurora went on to sell tens of thousands of dosage units of oxycodone and hydrocodone to a pharmacy run by the same man McKesson-Aurora had just been punished for failing to monitor. Also predictably, that same man proceeded to run a drug-trafficking organization out of his pharmacy, and people were killed by the narcotics that his drug-trafficking organization dispensed.

Before we pursue litigation, I am willing to meet with you to discuss the allegations outlined in this letter. I am willing to provide you with the opportunity to present facts that may be relevant to the resolution of this matter. I am also open to discussing settlement prior to initiating a civil action in federal district court. If you are interested in discussing this matter, please contact me at your earliest convenience, but no later than August 26, 2014. I can be reached at (303) 454-0109. I look forward to hearing from you.

Sincerely,

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